	<b>SAFETY DATA SHEET ACCORDING TO REG. EU 1907/2006</b>	Review n°: 07
	<b>GINEXID® Schiuma detergente ginecologica</b>	Date: 12/06/2015  1 of 15

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

<b>1.1 Product identifier</b>	GINEXID® Schiuma detergente ginecologica
<b>1.2 Relevant identified uses of the substance or mixture and uses advised against</b>	Cleansing foam at pH 4.5 is indicated for the daily hygiene even in the presence of pathologies (Bacterial and fungal vulvites) and / or in association with specific treatments
<b>1.3 Details of the supplier of the safety data sheet</b>	<p style="text-align: center;"><b>Producer / supplier</b> FARMA-DERMA S.R.L.</p> <p style="text-align: center;"><b>Address</b> Via dei Bersaglieri, 10 - 40100 Sala Bolognese (BO) ITALIA</p> <p style="text-align: center;"><b>telephone number</b> +39 051.6814181</p> <p style="text-align: center;"><b>Fax number</b> +39 051.6814833</p> <p style="text-align: center;"><b>Mail</b> -</p>
<b>1.4 Emergency telephone number</b>	+39 051.6814181 – MON-TUE-WED-THU-FRI 08.30AM - 1.00PM 2.00PM – 5.00PM – SAT-SUN closed.

## 2. HAZARDS IDENTIFICATION


<b>2.1 Classification of the mixture</b>	<p>The product is a COSMETIC (as defined by Regulation (CE) 1223/2009) and does not fall within scope of Regulation (CE) 1272/2008 CLP on the classification of dangerous mixtures.</p> <p>The product is in the form of aerosol generator and so it is classified and labeled in accordance with Directive 75/324/EEC and further modifications, which refers to Regulation (CE) 1272/2008</p> <p><b>Classification (Regulation (CE) n° 1272/2008)</b> H229 - Pressurised container: May burst if heated.</p>
<b>2.2 Label elements</b>	<p>GHS Pictograms: none</p> <p>Signal word: ATTENTION</p> <p>Risk statements: H229 - Pressurised container: May burst if heated.</p> <p>Precautionary statements:</p> <p>P102 - Keep out of the reach and sight of children</p> <p>P210 - Keep away from heat/sparks/open flames/hot surfaces. — No smoking.</p> <p>P251 - Do not pierce or burn, even after use</p> <p>P410+P412 - Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.</p> <p>7% by mass of the contents are flammable</p>
<b>2.3 Other hazards</b>	<p>Avoid contact with eyes</p> <p>Do not swallow</p>

For the full text, see Section 16

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

### 3.2 Mixtures

	<b>SAFETY DATA SHEET ACCORDING TO REG. EU 1907/2006</b>	Review n°: 07
	<b>GINEXID® Schiuma detergente ginecologica</b>	Date: 12/06/2015  2 of 15

Alchols, C10-16, ethoxylated, sulfosuccinates,  
disodium salts

CAS 68815-56-5

EINECS 500-232-7

REACH registration number -

Classification (Reg 1272/2008/EC) - CLP H318 – Eye Dam. 1

[%] < 10

Hydrocarbons, C3-C4 (Propane, Isobutane,  
N-butane mixture)

CAS 68476-40-4

EINECS 270-681-4

REACH registration number 01-2119486557-22-XXXX

Classification (Reg 1272/2008/EC) - CLP H220 - Flammable Gas cat 1  
H280 – Gas under pressure: liquefied gas. May explode if heated

[%] 7

This mixture contains 1.3 butadiene <0.1%, H<sub>2</sub>S (hydrogen sulfide <0.1% and CO (carbon monoxide <0.3%)

Sulfuric acid, mono-C12-16-alkyl esters,  
ammonium salts

CAS 90583-12-3

EINECS 292-210-6

REACH registration number 01-2119519217-42

Classification (Reg 1272/2008/EC) - CLP H290 - Met. Corr. 1  
H302 - Acute Tox. 4 (orale)  
H315 - Skin Corr./Irrit. 2  
H318 - Eye Dam./Irrit. 1  
H412 - Aquatic Chronic 3

[%] < 5

Undecylenamido propyl betaine

CAS 98501-75-9

EINECS 308-783-3


REACH registration number -

Classification (Reg 1272/2008/EC) - CLP H318 – Eye Dam. 1

[%] < 2

Aqueous dispersion of a polymer based on:  
1H-Imidazolium, 1-ethenyl-3-methyl-, methyl  
sulfate,  
polymer with 1-ethenyl-2-pyrrolidinone

CAS -

	<b>SAFETY DATA SHEET ACCORDING TO REG. EU 1907/2006</b>	Review n°: 07 Date: 12/06/2015
	<b>GINEXID® Schiuma detergente ginecologica</b>	3 of 15

EINECS -

REACH registration number -

Classification (Reg 1272/2008/EC) - CLP H411 – Aquatic Chronic 2

[%] < 1

Lactic Acid

CAS 79-33-4

EINECS 201-196-2

REACH registration number 01-2119474164-39-0000

Classification (Reg 1272/2008/EC) - CLP H315 – Skin Irr 2  
H318 – Eye Dam. 1

[%] < 1

Cocamidopropyl Betaine

CAS 147170-44-3

EINECS 931-333-8

REACH registration number 01-2119489410-39-0001

Classification (Reg 1272/2008/EC) - CLP H318 – Eye Dam. 1

Classification(according to Directives Xi; R41  
67/548/EEC or 1999/45/EC)

[%] < 1

L-Menthol

CAS 2216-51-5

EINECS 218-690-9

REACH registration number -

Classification (Reg 1272/2008/EC) - CLP H315 – Skin Irr 2  
H319 – Eye Irr. 2  
H335 – May cause respiratory irritation

[%] < 0,3


For the full text, see Section 16

## 4. FIRST AID MEASURES

### 4.1 Description of first aid measures

**Skin contact:** take-off contaminated clothing. Wash skin with plenty of soap and water. Get medical attention if it occurs irritation

**Eyes contact:** rinse thoroughly with plenty of water. Remove any contact lenses. Eyelids should be held away from the eyeball to ensure thorough rinsing. Get medical attention if you develop irritation.

	<b>SAFETY DATA SHEET ACCORDING TO REG. EU 1907/2006</b>	Review n°: 07
	<b>GINEXID® Schiuma detergente ginecologica</b>	Date: 12/06/2015  4 of 15

**ingestion;** Rinse mouth with water in order to dilute the product, do not induce vomiting. Get medical attention immediately.

**Inhalation:** move the victim to fresh air, remove contaminated clothing, and if breathing is difficult Get medical attention immediately.

**4.2 Most important symptoms and effects, both acute and delayed**

Inhalation: May cause fainting. Contains asphyxiant gas  
 Contact with eyes and skin: the contact with the liquefied gas or cold vapors can cause injury  
 Chronic Effects: None

**4.3 Indication of any immediate medical attention and special treatment needed**

None

**5. FIREFIGHTING MEASURES**

**5.1 Extinguishing media**

Suitable extinguishing media:  
 In case of fire, should be used carbon dioxide extinguishers, powder, vaporized liquid or sand.  
 Extinguish material unsuitable for safety reasons:  
 water jet, water jet nebulized.

**5.2 Special hazards arising from the mixture**

Combustion Products: Smoke, CO and CO2 and other harmful vapors

**5.3 Advice for firefighters**

Cool the containers with water to prevent product decomposition and the development of potentially dangerous substance. Always wear full fire prevention equipment. Extinguishing water collected must not be discharged into drains. Dispose of the materials used for extinction according to current regulations.

**6. ACCIDENTAL RELEASE MEASURES**

**6.1 Personal precautions, protective equipment and emergency procedures**

If necessary wear breathing apparatus, suitable protective clothing such as safety glasses, gloves, etc., remove all sources of ignition and do not smoke. Wash hands after use

**6.2 Environmental precautions**

Contain the spill with an absorbent material such as sand or ground. Do not allow product to contaminate waterways, groundwater and soil. In case of such events notify this to the competent authorities.

**6.3 Methods and material for containment and cleaning up**

Containment: Absorb with inert material (eg sand or absorbent mold/soil). Reclamation: provide good ventilation and let the product evaporate. Wash with water if necessary and / or suitable detergent avoiding solvents. Collect material in suitable containers and dispose of in accordance with current regulations

**6.4 Reference to other sections**

Please observe the information in other chapters. in particular for information on personal protection equipment (Chapter 8) and disposal (Chapter 13)


**7. HANDLING AND STORAGE**

**7.1 Precautions for safe handling**

Shake the bottle well before use and keep it in an upright position during delivery. Cleanse the external genital mucosa and rinse with water.

**7.2 Conditions for safe storage, including any incompatibilities**

Keep out of the reach and sight of children  
 Keep away from heat/sparks/open flames/hot surfaces. — No smoking.  
 Do not pierce or burn, even after use  
 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 ° F.

	<b>SAFETY DATA SHEET ACCORDING TO REG. EU 1907/2006</b>	Review n°: 07
	<b>GINEXID® Schiuma detergente ginecologica</b>	Date: 12/06/2015  5 of 15

### 7.3 Specific end use(s)

Cleansing foam at pH 4.5 is indicated for the daily hygiene even in the presence of pathologies (Bacterial and fungal vulvites) and / or in association with specific treatments

## 8. EXPOSURE CONTROL/PERSONAL PROTECTION

### 8.1 Control parameters

Occupational exposure limit values

Alkanes C1.C4 (ACGIH 2010): TLV-TWA 1000ppm

Derived No Effect Level (DNEL)

Sulfuric acid, mono-C12-16-alkyl esters, ammonium salts	Population	Route of exposure	Potential health effects	Value
	Workers	Skin contact	Long term exposure Systemic effects	4060 mg/kg
		Inhalation	Long term exposure Systemic effects	285 mg/m <sup>3</sup>
	Consumer	Skin contact	Long term exposure Systemic effects	2440mg/kg
		Inhalation	Long term exposure Systemic effects	85 mg/m <sup>3</sup>
		Ingestion	Long term exposure Systemic effects	24 mg/kg


The predicted no-effect concentration (PNEC)

Sulfuric acid, mono-C12-16-alkyl esters, ammonium salts	Compartment	Value
	Soft water	0,1016 mg/l
	Sea water	0,01016 mg/l
	emission occasional	0,036 mg/l
	treatment plant	1084 mg/l
	Soft water sediment	3,58 mg/kg
	Seawater sediment	0,358 mg/kg
	Soil	0,654 mg/kg

### 8.2 Exposure controls

Personal protective equipment

General protective and hygienic measures Keep from food, beverages and feed.

	<b>SAFETY DATA SHEET ACCORDING TO REG. EU 1907/2006</b>	Review n°: 07
	<b>GINEXID® Schiuma detergente ginecologica</b>	Date: 12/06/2015  6 of 15

Immediately remove all contaminated clothes.  
Wash hands before breaks and after work.  
Avoid contact with eyes.

Protective mask not required

Protective gloves not required

Protective eyewear not required. Avoid contact with eyes.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

**Appearance** foam

**Odour** Typical of menthol

**Color** colourless, slightly yellow

**Odour threshold;** no data available

**pH** 4,20 - 5,00

**Melting point/freezing point;** no data available

**Initial boiling point and boiling range** no data available

**Flash point** no data available

**Evaporation rate** no data available

**Flammability (solid, gas)** non flammable

**Upper/lower flammability or explosive limits** no data available

**Specific weight** 1,017 - 1,040 g/ml

**Vapour pressure** no data available

**Vapour density;** no data available

**Relative density** no data available

**Solubility(ies)** no data available

**Partition coefficient: n-octanol/water** no data available

**Auto-ignition temperature** no data available

**Decomposition temperature** no data available

**Viscosity** no data available

**Explosive properties** no data available

**Oxidising properties** no data available


### 9.2 Other information

-

## 10. STABILITY AND REACTIVITY

### 10.1 Reactivity

This product has no additional hazards related to reactivity than those described below.

	<b>SAFETY DATA SHEET ACCORDING TO REG. EU 1907/2006</b>	Review n°: 07
	<b>GINEXID® Schiuma detergente ginecologica</b>	Date: 12/06/2015  7 of 15

<b>10.2 Chemical stability</b>	The product is stable under normal use. Avoid heat and oxidizing agents
<b>10.3 Possibility of hazardous reactions</b>	Contact with strong oxidizing agents or exposure to high temperatures can cause a fire hazard
<b>10.4 Conditions to avoid</b>	Keep away from oxidizing agents. Prevent the accumulation of electrostatic charges. Keep away from heat, sparks, open flames
<b>10.5 Incompatible materials</b>	strong oxidizing agent
<b>10.6 Hazardous decomposition products</b>	The product does not decompose if used in an appropriate way

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### Product data

**acute oral - toxicity** Ingestion may cause health problems, including stomach pain with burns, nausea and vomiting.

**Skin corrosion/irritation** classified as NOT IRRITATING – patch test  
classified as NOT CORROSIVE - patch test

**Serious eye damage/irritation** Causes serious eye damage

**Sensitization of the respiratory tract or the skin** Contains substances classified as skin sensitizers in compliance with provisions of regulation 1223/2009

**Germ cell mutagenicity** The chemical structure of single components does not determine any particular suspicion of such effect.

**Carcinogenicity** The chemical structure of single components does not determine any particular suspicion of such effect.

**Reproductive toxicity** The chemical structure of single components does not determine any particular suspicion of such effect.

**STOT-single exposure** Based on the available data, the criteria for classification are not satisfied

**STOT-repeated exposure** None know


**Aspiration hazard** Do not swallow

#### Substances data

**Alchols, C10-16, ethoxylated, sulfosuccinates, disodium salts**

**acute oral - toxicity** Almost nontoxic after a single ingestion.  
Experimental / calculated data:  
LD50 > 2000 mg/kg body weight - Method: Directive 84/449/EEC B.1

**skin corrosion/irritation** Assessment of irritating effects:  
Not irritating to the skin.  
Experimental / calculated data:  
Corrosione / irritation rabbit: non – irritant (OECD Guideline 404)

	<b>SAFETY DATA SHEET ACCORDING TO REG. EU 1907/2006</b>	Review n°: 07
	<b>GINEXID® Schiuma detergente ginecologica</b>	Date: 12/06/2015  8 of 15

**serious eye damage/irritation** Assessment of irritating effects:  
Risk of serious damage to eyes.  
Experimental / calculated data:  
Serious damage to eyes / eye irritation rabbit: strong irritant (OECD Guideline 405)

**respiratory or skin sensitisation** Assessment of sensitization:  
There is no evidence of a potential sensitizing effect on the skin.

**germ cell mutagenicity** Assessment of mutagenicity:  
The chemical structure does not determine any particular suspicion of such an effect.  
Experimental / calculated data:  
Ames test  
Bacteria: negative (OECD - guideline 471)

**carcinogenicity** Assessment of carcinogenicity:  
The chemical structure does not determine any particular suspicion of such an effect.

**reproductive toxicity** Assessment of reproduction toxicity:  
The chemical structure does not determine any particular suspicion of such an effect.

**Developmental Toxicity** Assessment of teratogenicity:  
No data are available on teratogenic effects.

**STOT-single exposure** Assessment of single STOT:  
On the basis of available data, the criteria for classification are not met.

**STOT-repeated exposure** Assessment of toxicity following repeated administration:  
None known

**aspiration hazard** It is not expected any risk of aspiration.

**Hydrocarbons, C3-C4 (Propane, Isobutane, N-butane mixture)**


**Acute oral and skin toxicity** The product is a gas at room temperature and pressure, therefore oral and dermal toxicity considerations are not available

**Acute toxicity - inhalation** RAT - inhalation (1)  
LC50 (15 min): 800000 ppm (males / females)  
LC50 (15 min): 14442738 mg/m<sup>3</sup> (males / females)  
LC50 (15 min): 1443 mg/l (males / females)  
The smell is not detectable under 20,000 ppm (2%) and a concentration of 100,000 ppm produced slight irritation to eyes and respiratory system but caused slight dizziness in a few minutes (2)

**Skin corrosion/irritation** Certain dose-response studies in humans show that propane and butane have not irritant and corrosive effects on skin and mucous membranes. Contact with liquefied gas may cause burns from cold

**Respiratory or skin sensitisation** There are no available studies that indicate this type of effect



	<b>SAFETY DATA SHEET ACCORDING TO REG. EU 1907/2006</b>	Review n°: 07 Date: 12/06/2015
	<b>GINEXID® Schiuma detergente ginecologica</b>	9 of 15

**CMR** No evidence of genotoxicity. In addition, the product contains 1,3 butadiene <0.1% therefore is not classified as mutagenic in accordance with current European regulations.  
Test in Vitro - test Ames in Salmonella strains (OECD TG 471): negative (3)  
Test in Vitro - test Ames in Salmonella typhimurium (OECD TG 471): negative (4)  
Test in Vivo - micronucleus test RAT - inhalation (OECD Guideline 474): negative (5)

No evidence of carcinogenicity. In addition, the product contains 1,3 butadiene <0.1% therefore is not classified as carcinogen according to local regulations.

Reproductive toxicity: most of the studies conducted for the REACH registration dossier showed no consistent evidence of toxicity for fertility, therefore the product is not classified as toxic to reproduction in accordance with EU regulations.

In vivo study - RAT - 13 week inhalation exposure., 6 h / d., 5 d / wk.) (OECD Guideline 413 EPA OPPTS 870.3465 (90): NOAEC: 10000 ppm (M / F) No effect on the menstrual cycle, on spermatogenesis, sperm count and mobility (6)

Developmental toxicity / teratogenicity: Most studies have not shown consistent evidence of developmental toxicity / teratogenicity. In addition, the product does not contain carbon monoxide in concentrations higher than 0.2%, therefore it is not classified toxic to reproduction in accordance with current European regulations

In vivo study - RAT - Inhalation Exposure M: 2 weeks. prior to mating and 28 d. (minimum) after mating F: 2 weeks. prior to mating 0-19 g. of gestation 6 h / d., 5 d. per wk. Concentrations: 0, 1600, 5000 and 16000 ppm (OECD Guideline 422 EPA OPPTS 870.3650) NOAEC (maternal toxicity): 16000 ppm (no effects of systemic toxicity at the highest concentration tested) NOAEC (maternal toxicity): 19678 mg / m<sup>3</sup> air NOAEC (developmental toxicity): 16000 ppm (no effect on the development) NOAEC (developmental toxicity): 19678 mg / m<sup>3</sup> air (7)

**STOT-single exposure** no data available

**STOT-repeated exposure** Inhalation

Methane: There is no dose-response studies


Propane: In a study conducted over a period of 6 weeks in male and female rats were not observed neurological effects, haematological, or clinical. At doses of 12,000 ppm male animals showed a decrease of 25% of weight during the first week of exposure.

The lowest concentration at which adverse effects were observed (LOAEC) in this study is 12,000 ppm (equivalent to 21,641 mg/m<sup>3</sup>).

**Aspiration hazard** no data available

**Sulfuric acid, mono-C12-16-alkyl esters,  
ammonium salts**

**acute oral - toxicity** LD50 (Orale): > 2000 mg/kg Rat

	<b>SAFETY DATA SHEET ACCORDING TO REG. EU 1907/2006</b>	Review n°: 07
	<b>GINEXID® Schiuma detergente ginecologica</b>	Date: 12/06/2015  10 of 15

**skin corrosion/irritation** rabbit: Irritant. (OECD Guideline 404)

**serious eye damage/irritation** Rabbit: severely irritating. (OECD Guideline 405)

**respiratory or skin sensitisation** There is no evidence of a potential sensitizing effect on the skin.

**germ cell mutagenicity** The chemical structure does not determine any particular suspicion of such effect.

Ames test

Bacteria: negative (OECD - guideline 471)

**carcinogenicity** The chemical structure does not determine any particular suspicion of such effect.

**reproductive toxicity** The chemical structure does not determine any particular suspicion of such effect.

**Developmental Toxicity** Assessment of teratogenicity:  
No data are available on teratogenic effects.

**STOT-single exposure** Based on the available data , the criteria for classification are not satisfied

**STOT-repeated exposure** none known

**aspiration hazard** It is not expected any risk of aspiration

#### Undecylenamido propyl betaine

**acute oral - toxicity** LD50 > 2000 mg/kg (rat)

**skin corrosion/irritation** Corrosive effect on skin and mucous membranes

**serious eye damage/irritation** strong corrosive

**respiratory or skin sensitisation** There is no evidence of a potential sensitizing effect

#### Aqueous dispersion of a polymer based on:

1H-Imidazolium, 1-ethenyl-3-methyl-,  
methyl sulfate,

polymer with 1-ethenyl-2-pyrrolidinone

**acute oral - toxicity** LD50 rat (oral): > 2,000 mg/kg (OECD Guideline 423)

**skin corrosion/irritation** Not irritating (OECD Guideline 404)

**serious eye damage/irritation** Not irritating (OECD Guideline 405)

**respiratory or skin sensitisation** There is no evidence of a potential sensitizing effect (OECD Guideline 406)

#### Lactic Acid

**acute oral - toxicity** LD50 (oral-mous) 4875 mg/kg

**acute skin - toxicity** LD 50 (derm-rabb) > 2000 mg/Kg

**acute inhalation – toxicity** 7,94 mg/l/4h rat


**skin corrosion/irritation** Causes skin irritation (rabbit)

**serious eye damage/irritation** Causes serious eye damage (rabbit)

**germ cell mutagenicity** The bacterial tests did not show any mutagenic activity

#### Cocamidopropyl Betaine

**acute oral - toxicity** 8100 mg/kg Rat

	<b>SAFETY DATA SHEET ACCORDING TO REG. EU 1907/2006</b>	Review n°: 07
	<b>GINEXID® Schiuma detergente ginecologica</b>	Date: 12/06/2015  11 of 15

**acute skin - toxicity** Not irritating

**skin corrosion/irritation** Irritating

**germ cell mutagenicity** Not mutagenic effects (Ames Test)

**respiratory or skin sensitisation** Not sensitising

#### L-Menthol

**acute oral - toxicity** 3300 mg/kg (rat)

**acute skin - toxicity** >5000 mg/kg (rabbit)

**skin corrosion/irritation** Irritating

**serious eye damage/irritation** Irritating

**respiratory or skin sensitisation** There is no evidence of a potential sensitizing effect

## 12. ECOLOGICAL INFORMATION

Ecotoxicological data on the mixture are not available. Following are shown ecotoxicological information regarding the main substances in the mixture

### 12.1 Toxicity

#### Alcohols, C10-16, ethoxylated, sulfosuccinates, disodium salts

The product has not been tested. The indication is given on the basis of the properties of individual components.

Toxicity to fish:  
 CL50 > 10 - 100 mg/l (DIN EN ISO 7346-2)  
 Microorganisms / Effect on activated sludge:  
 CE0 > 10 - 100 mg/l (OECD - guideline 209)

#### Hydrocarbons, C3-C4 (Propane, Isobutane, N-butane mixture)

This product is made from gaseous substances at room temperature and pressure, which are mainly distributed in the air rather than water sediment and soil.


Invertebrates - Daphnia Short Term LC50 48 / h: 14,22 mg / l Key study CAS 106-97-8 (Butane) USEPA OPP (2008)  
 Invertebrates - Daphnia Short Term LC50 48 / h: 69,43 mg / l Key study CAS 74-82-8 (Methane) QSAR USEPA OPP (2008)  
 Short-term Algae EC50 (96 h): 19,37 mg / l Key study CAS 74-82-8 (Methane) QSAR  
 Short-term fish LC50 96 / h: 147,54 mg / l Key study CAS 74-82-8 (Methane) QSAR EPA 2008  
 Short-term fish L50 96 / h: 24,11 mg / l Key study CAS 106-97-8 (Butane) QSAR EPA 2008

#### Sulfuric acid, mono-C12-16-alkyl esters, ammonium salts


Toxicity to fish:  
 LC50 > 1 - 10 mg / l (DIN EN ISO 7346-2)  
 Microorganisms / Effect on activated sludge:  
 CE0 > 10-100 mg/l, (DIN 38412 parte 27)

#### Cocamidopropyl Betaine

LC50 (96h): 25 mg/l *Leuciscus idus*  
 EC50 (48h): 45 mg/l *Daphnia*

	<b>SAFETY DATA SHEET ACCORDING TO REG. EU 1907/2006</b>	Review n°: 07
	<b>GINEXID® Schiuma detergente ginecologica</b>	Date: 12/06/2015  12 of 15

<b>Aqueous dispersion of a polymer based on: 1H-Imidazolium, 1-ethenyl-3-methyl-, methyl sulfate, polymer with 1-ethenyl-2-pyrrolidinone</b>	LC50 (96 h) 14.8 mg/l, Brachydanio rerio (OECD Guideline 203) EC50 (48 h) 1 - 10 mg/l, Daphnia magna (OECD Guideline 202) EC50 (72 h) > 100 mg/l (growth rate), Desmodesmus subspicatus (OECD Guideline 201) EC20 (0.5 h) > 1,000 mg/l, activated sludge, domestic (OECD Guideline 209)
<b>Lactic Acid</b>	EC50 (48h) 240 mg/l daphnia magna
<b>L-Menthol</b>	IC50/nn 237 mg/l (bacteria) LC0/96 h 16 mg/l (fish)
<b>12.2 Persistence and degradability</b>	
<b>Alcohols, C10-16, ethoxylated, sulfosuccinates, disodium salts</b>	Readily biodegradable (according to 648/2004).
<b>Hydrocarbons, C3-C4 (Propane, Isobutane, N-butane mixture)</b>	abiotic degradation This product can contribute to the formation of ozone in the atmosphere near the surface. However, the photochemical formation of ozone depends on a complex interaction of air pollutants and other environmental conditions. Biotic degradation: QSAR studies were conducted with ethane which has a biodegradability of 100% in 16 days. The ethane is not a component of the gas oil but its structure is representative of the stream, and can be a read-across, therefore on the basis of the above product is biodegradable.
<b>Sulfuric acid, mono-C12-16-alkyl esters, ammonium salts</b>	Readily biodegradable (according to 648/2004).
<b>Cocamidopropyl Betaine</b>	Readily biodegradable (according to 648/2004).
<b>Aqueous dispersion of a polymer based on: 1H-Imidazolium, 1-ethenyl-3-methyl-, methyl sulfate, polymer with 1-ethenyl-2-pyrrolidinon</b>	Not readily biodegradable (by OECD criteria). Easily removed from the water for absorption on activated sludge. The product has not been tested. The indications are given on the basis of substances / products of a similar structure or composition. Disposal considerations: 90-100% reduction of DOC (3 h) (ISO 18749) (aerobic, activated sludge, domestic)
<b>12.3 Bioaccumulative potential</b>	
<b>Hydrocarbons, C3-C4 (Propane, Isobutane, N-butane mixture)</b>	The log Pow for GPL is estimated in the range from 1,09 to 2,8, so the product does not bioaccumulate.
<b>12.4 Mobility in soil</b>	
<b>Hydrocarbons, C3-C4 (Propane, Isobutane, N-butane mixture)</b>	Absorption Koc: Standard tests for this endpoint are not applicable to UVCBs
<b>Aqueous dispersion of a polymer based on: 1H-Imidazolium, 1-ethenyl-3-methyl-, methyl sulfate, polymer with 1-ethenyl-2-pyrrolidinon</b>	Absorption to the solid phase of the soil is possible.
<b>Chlorehexidine digluconate</b>	log KOC > 3,9 (OECD TG 121)
<b>12.5 Results of PBT and vPvB assessment</b>	The product does not contain any relevant substances evaluated as persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative

	<b>SAFETY DATA SHEET ACCORDING TO REG. EU 1907/2006</b>	Review n°: 07 Date: 12/06/2015
	<b>GINEXID® Schiuma detergente ginecologica</b>	13 of 15

12.6 Other adverse effects not known

### 13. DISPOSAL CONSIDERATIONS

**13.1 Waste treatment methods** Recover if possible or send to approved plants or to incineration under controlled conditions.  
For handling and measures in case of accidental release of waste, apply in general to the information provided in sections 6 and 7.  
Precautions and specific actions must be assessed in relation to the composition of the waste.  
Operate according to local and national regulations.

### 14. TRANSPORT INFORMATION

**4.1 UN number** 1950

**14.2 UN proper shipping name** ADR / IMDG / IATA: Aerosol asphyxiant

**14.3 Transport hazard class(es)** ADR: 2  
IMDG: 2  
IATA: 2

**14.4 Packing group** N/A

**14.5 Environmental hazards** None

**14.6 Special precautions for user** Code EmS: F-D, S-U

**14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** N/A


### 15. REGULATORY INFORMATION \*

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture** Regulation (CE) n° 1907/2006/CE (REACH)  
Regulation (CE) n° 1272/2008/CE (CLP) and following ATP  
Regulation (CE) n° 453/2010/CE (concerning the preparation of safety data sheets)  
Regulation 830/2015/CE concerning the preparation of safety data sheets)  
D.Lgs 81/2008 ( consolidated text on health protection and safety in the workplace) and further modifications  
Directive 75/324/CE (concerning aerosol ) and further modifications  
Regulation (CE) n°1223/2009

**15.2 Chemical safety assessment** no data available

### 16. OTHER INFORMATION

List of relevant Hazard statements

	<b>SAFETY DATA SHEET ACCORDING TO REG. EU 1907/2006</b>	Review n°: 07
	<b>GINEXID® Schiuma detergente ginecologica</b>	Date: 12/06/2015  14 of 15

H220 - Extremely flammable gas. Cat. 1  
 H226 - Flammable liquid and vapour. Cat 3  
 H229 – Aerosol Cat 3  
 H280 - Contains gas under pressure; may explode if heated.  
 H302 – Harmful if swallowed cat 4  
 H304 - May be fatal if swallowed and enters airways Cat 1  
 H315 - Causes skin irritation. Cat 2  
 H317 - May cause an allergic skin reaction. Cat 1  
 H318 – Causes serious eye damage Cat 1  
 H319 - Causes serious eye irritation. Cat 2  
 H335 – May causes respiratory irritation Cat 3  
 H400 – Very toxic for aquatic life Cat 1  
 H410 - Very toxic to aquatic life with long lasting effects. Cat 1  
 H411 - Toxic to aquatic life with long lasting effects. Cat 2

*ACGIH = American Conference of Governmental Industrial Hygienists*

*CSR = Chemical safety Report*

*DNEL = Derived no-effect level*

*EC50 = half maximal effective concentration*

*LC50 = inhibition concentration, 50%*

*LC50 = lethal concentration, 50%*

*LD50 = Lethal dose*

*PNEC = Predicted no effect concentration*

*n.a. = not applicable*

*PBT = Persistent, Bioaccumulative, Toxic*

*STOT = Single Toxicity Organ target*

*(STOT) RE = Repeated exposure*

*(STOT) SE = single exposure*

*TLV-TWA = Threshold limit value - time weighted average*


*TLV-STEL = Threshold limit value – short term exposure limit*

*UVCB = substances of Unknown or Variable composition*

*vPvB = very persistent and very bioaccumulative*

## Bibliography

- (1) Clark DG and Tiston DJ(1982)
- (2) Anon 1982 Herman (Chairman 1966)
- (3) National Toxicology Program (1993)
- (4) Kirwin CJ and Thomas WC (1980)
- (5) Huntingdon Life Sciences (HLS) (2009b)
- (6) Huntingdon Life Sciences (HLS) (2009b)
- (7) Huntingdon Life Sciences (HLS) (2010a)

	<b>SAFETY DATA SHEET ACCORDING TO REG. EU 1907/2006</b>	Review n°: 07  Date: 12/06/2015
	<b>GINEXID® Schiuma detergente ginecologica</b>	15 of 15

\* Section revised

15

*The data and information relates only to the specific product.*

*The information is based on the knowledge in our possession in accordance with the current state and all applicable laws.*

*The user has the responsibility to use the product according to the instructions and take all necessary steps to meet the requirements of the laws and regulations relating to health, safety and hygiene at work, respect for the environment.*

*We decline all responsibility for damage caused by improper use of the product.*